

USSN 08/495,724
February 6, 1997
Page 2

REMARKS**I. Claims In The Application**

Applicants provisionally elect, with traverse, prosecution of claims 1, 2, 4 and 27, which are directed to methods of using IL-11 to treat rheumatoid arthritis. For the convenience of the Examiner, attached is a compilation of the pending claims.

**II. Supplemental Information
Disclosure Statement and
Accompanying Form PTO-1449**

In accordance with the provisions of 37 CFR §1.56 and §1.97, attached hereto is supplemental form PTO 1449 which lists references cited in the PCT/US96/08059 International Search Report dated November 6, 1996. Copies of the references are attached, as well as a copy of the International Search Report.

In accordance with the provisions of 37 CFR §1.97, this statement is being filed before the mailing date of a **Final Rejection or Notice of Allowance**, and the requisite fee under §1.17(p), namely \$230.00, can be charged to Deposit Account 07-1060.

Accordingly, the Commissioner is hereby authorized to charge the fee of \$230.00 and any additional fees due with this paper, to Deposit Account 07-1060. Triplicate copies of this transmittal letter are enclosed.

The Examiner is requested to consider the attached documents during the course of the examination of this application and that each of the documents shown on the attached form PTO-1449 be made of record in this application.

No representation is made hereby that these documents provide all of the art and the Examiner is presumed to conduct an independent search of the art. However, these documents do form all of the relevant art of which Applicants are presently aware. Should Applicants become aware of additional

USSN 08/495,724
February 6, 1997
Page 3

relevant art during the prosecution of this application, Applicants will bring such art to the attention of the Examiner by means of a supplemental Information Disclosure Statement.

III. Patentability Arguments

Claims 1, 2, 4 and 27 are rejected under §112, first paragraph. In light of the arguments and attached Declaration of Dr. Keith, a proper basis exists for withdrawal of the rejection.

The sole issue with respect to the rejection of these method claims is whether the application, as filed, teaches one skilled in the art how to use IL-11 to treat rheumatoid arthritis. The concerns raised by the Examiner appear to relate more to whether the claimed invention will work, not to "how to use" the claimed invention. "How to use" is clearly enabled by the specification as filed, as exemplified at page 12, lines 15-34 (describing the use of IL-11 in treatment of arthritis); page 10, lines 26 *et seq.* (describing in detail exemplary carriers); and page 11 (describing in detail suitable formulations, doses and treatment regimens). Even doses of 1 to 100, 10 to 50; 50; and 20 micrograms of IL-11/kilogram of body weight are taught. See also, the attached Declaration of Dr. James Keith, one who is skilled in the art, concluding that one of ordinary skill in the art is provided with sufficient guidance in the specification, as of the date the specification was filed, to enable one skilled in the art to use IL-11 to treat rheumatoid arthritis.

The art relied upon by the Examiner relates more to whether the claimed invention will work. However, cited are *in vitro* IL-11 studies (Feldman and Girasole). Applicants' studies are *in vivo* and clearly demonstrate IL-11 efficacy in treating rheumatoid arthritis.

As for Paul (W) and Brennan (X), who state that no animal model has all the features of rheumatoid arthritis, in fact, the model Applicants use is an animal model that does have all the features of chronic rheumatoid arthritis. See Hammer, *et al.*, Cell 63:1099-1112 (1990) (Exhibit 1) and the attached Declaration of Dr. James Keith.

USSN 08/495,724
February 6, 1997
Page 4

Clearly, the animal model Applicants utilized is appropriate and the claimed invention, the administration of IL-11 to reduce joint inflammation, is effective.

In light of the specification disclosure and the Declaration of Dr. James Keith, the lack of enablement rejection may properly be withdrawn.

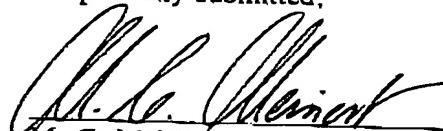
CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of record and issuance of the claims as amended.

Should the Examiner believe that a telephonic interview would assist in clarifying any remaining issues, or to otherwise expedite prosecution, Applicants respectfully invite the Examiner to call the undersigned attorney at the telephone number provided below.

If any additional fee is due with regard to this paper, Applicants hereby authorize payment of such fee from Deposit Account-No. 07-1060.

Respectfully submitted,



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